7.0 PREMARKET NOTIFICATION 510(K) SUMMARY

APR 0 8 2003

Sponsor:

EnVän LLC
P.O. Box 660827
Birmingham, Alabama 35266
Telephone: (205) 824-2280
Fax: (205) 824-2278
Contact: Swaid N. Swaid, MD, FACS

Manufacturer:

EnVän LLC
P.O. Box 660827
Birmingham, Alabama 35266
Telephone: (205) 824-2280
Fax: (205) 824-2278
Contact: Swaid N. Swaid, MD, FACS

Registration: To be assigned

Contact Person:

Marie Marlow
M Squared Associates, Inc.
719 A Street, NE
Washington DC 20002
Telephone: 202-546-1262
Fax: 202-546-3848
E-mail: mmarlow@msquaredassociates.com

Trade Name of Device: EnVän Heart Rate Monitor
Common Name: Heart Rate Monitor
Classification name: Cardiac Monitor (including cardiotachometer and rate alarm)
Product Code: DRT
Regulation Class: II
Regulation Number: §870.2300

Device Description: The EnVän Heart Rate Monitor is currently marketed as a consumer product for use as a sports training aid, and intended for use in conjunction with either exercise devices or

exercise routines with no medical indications. Clearance of this 510(k) premarket notification will allow the device to be labeled for use to measure heart rate in patients who require routine, periodic vital signs monitoring.

Indications for Use: The EnVän Heart Rate Monitor is indicated for use to measure the heart rate of patients who require routine periodic vital signs monitoring. It is intended to provide heart rate information on a wristwatch display for interpretation by a healthcare professional in a hospital, outpatient or ambulatory care setting. It is neither designed nor intended for use in the place of cardiac (electrocardiograph) monitoring.

The EnVän Heart Rate Monitor is not suitable for use within emergency rooms, intensive care or cardiac care units, or operating room or post anesthesia units where cardiac monitors, pacemakers and other types of electrical or electronic medical devices are in use. These devices may interfere with the operation of the EnVän Heart Rate Monitor.

Major Components: Heart rate signals are acquired and transmitted by conductive synthetic rubber pads (IndePad™) then processed and displayed on a digital wristwatch worn by the healthcare professional. The heart rate display on the screen is updated every few seconds, to assure an accurate measurement of heart rate.

Basis for Substantial Equivalence

Predicate Devices: Criticare Systems Vital Signs Monitor (K022435) and Masimo SET® Radical Pulse Oximeter (K992340)

- The EnVän Heart Rate Monitor has indications for use equivalent to those for the heart rate monitoring capabilities of the predicate devices.
- The EnVän Heart Rate Monitor has technological characteristics, performance characteristics, and instructions for use equivalent to those for the heart rate monitoring capabilities of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 0 8 2003

EnVän, LLC
c/o Ms. Marie Marlow
President
M Squared Associates, Inc.
719 A Street, NE
Washington, DC 20002

Re: K030656
Trade Name: EnVän® Heart Rate Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: DRT
Dated: February 28, 2003
Received: March 3, 2003

Dear Ms. Marlow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Sponsor: EnVän

510(k) number: K030656
not yet assigned

Device Name: EnVän® Heart Rate Monitor

Indications for Use:

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(Division Sign-Off)
Division of Cardiovascular

510(k) Number K030656